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09/652,753	08/31/2000	Sonti Venkata Ramakrishna	U 012932-5	3517
7590 Ladas & Parry 26 West 61st Street New York, NY 10023			EXAMINER PADMANABHAN, KARTIC	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 20, 22-23, 25-28, 30-34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416).

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Ramakrishna et al. teach a process for the preparation of stable yeast crystals. According to the invention, yeast is grown by inoculation in media that was sterilized at 121 degrees Celsius after the pH had been adjusted to 6.8-7.2 using 1 N sodium chloride or 1 N hydrochloric acid. This was then incubated on a shaker at 26-30 degrees Celsius for about 24 hours with aeration. The yeast was then separated by centrifugation at 5,000-15,000 rpm for 10 minutes at 24-32 degrees Celsius. A yeast slurry was then prepared by mixing the yeast 0.5-10% with 0.5-3% natural polymer solution. The immobilized yeast beads were then prepared by adding this solution dropwise into a curing solution of 0.05-0.3 M calcium chloride solution. The beads were kept in this solution overnight at a temperature of 4 degrees Celsius. The immobilized yeast beads were then separated by decanting the solution and washed with distilled water several times. The beads were then dehydrated at a temperature of 24-36 degrees Celsius for 2-20 hours to obtain stable yeast crystals having a moisture content of 5-30%. These crystals were activated by incubation in 5-8% molasses solution for 2-48 hours at 24-32 degrees Celsius. The yeast crystals were then separated by draining this aqueous solution (Col. 4, lines 8-53). Sodium alginate 2% was generally used in preparing the yeast slurry (Col. 4, lines 64). However, the reference does not teach selecting a culture from activated sludge.

Yuan teaches the immobilization of microbial cells in polymeric beads. The process of the reference can be used effectively to immobilize yeast, as well as activated sludge microorganisms and waste water treatment microorganisms (Col. 2, line 63 – Col. 3, line 5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the microbial consortia obtained from wastewater treatment plants as taught by Yuan with the method of Ramakrishna et al. because Yuan teaches that both yeast and waste

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water microorganisms can be used for immobilization onto beads. Therefore, one could have substituted wastewater microorganisms for the yeast in Ramakrishna et al. with a reasonable expectation of success. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the specific aeration of 5 ml/minute. The selection of this parameter merely represents an optimization of the assay protocol and does not patentably distinguish the claimed invention over the prior art of record. One of skill in the art would easily be capable of selecting an appropriate aeration rate that promotes yeast growth. Further, the reference discloses the use of 1 N solutions to adjust pH, as opposed to 0.1 N as claimed. However, it would have been obvious to use 0.1 N solutions with the invention of the reference because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In this case, the use of a less concentrated solution allows for the concentration of the media to be adjusted at a more gradual rate than if using a more concentrated solution, with the selection of the preferred concentration well within the skill of those in the art.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Moreton et al. (US Pat. 4,778,630) and Shimizu et al. (US Pat. 4,355,111).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach the specific components of the growth media or glucose as the activation solution.

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Moreton et al. teach the use of a growth medium comprising potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate, yeast extract, glucose, ammonium chloride, and urea (Col. 4). The reference does not teach sodium bicarbonate or tryptone in media.

Shimizu et al. teach a growth medium comprising sodium bicarbonate and tryptone (claims).

It would have been *prima facie* obvious to one of ordinary skill in the art to use the growth media of Moreton et al. with the modified method of Ramakrishna et al. and Yuan because the selection of the growth media merely represents an optimization of the assay protocol that does not patentably distinguish the claimed invention over the prior art. One of skill in the art would easily be able to select an appropriate growth media for culturing various microorganisms. In addition, although Moreton et al. does not specifically teach tryptone, it allows for the use of other carbon sources, of which tryptone is an example, and Shimizu et al. teach the use of tryptone in media for the growth of microorganisms. In addition, Shimizu teaches sodium bicarbonate in media, which one of skill in the art could have easily substituted for the salts in the media of Moreton with a reasonable expectation of success, as calcium in calcium chloride and sodium in sodium bicarbonate are metals belonging to adjacent periods in the periodic table with similar properties. Furthermore, it would have been obvious to substitute dipotassium hydrogen orthophosphate for the disodium hydrogen orthophosphate in Moreton et al. because sodium and potassium belong to the same period in the periodic table, and one of skill in the art could reasonably expect them to have very similar properties.

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6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Husain et al. (US Pat. 6,361,695).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach the termination of growth at an MLSS of 14,500-15,500 mg/liter.

Husain et al. teach a wastewater treatment system wherein when the MLSS reaches levels of 15 g/l (15,000 mg/liter), some of the mixed liquor is removed from the bioreactor. The MLSS levels must be below this level for effective effluent treatment.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the MLSS levels of Husain et al. with the modified method of Ramakrishna et al. and Yuan because after an MLSS of 15,000 mg/liter has been reached, optimal conditions for effluent treatment and growth of microbes no longer exist.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ramakrishna et al. (US Pat. 6,420,146) in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Kikuta et al. (US Pat. 5,990,191).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach glucose as the activation solution.

Kikuta et al. teach a glucose solution for the activation of carriers with microorganisms immobilized thereon (Col. 10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute glucose as the activation solution as taught by Kikuta et al. for molasses as taught by Ramakrishna et al. because both are very well known carbon sources, and Kikuta et al. teach that glucose can be used for activation, which would provide one of skill in the art a reasonable expectation of success in making the substitution.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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9. Claims 20, 22-23, 25-28, 30-34, and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416).

Ramakrishna et al. teach a process for the preparation of stable yeast crystals. According to the invention, yeast is grown by inoculation in media that was sterilized at 121 degrees Celsius after the pH had been adjusted to 6.8-7.2 using 1 N sodium chloride or 1 N hydrochloric acid. This was then incubated on a shaker at 26-30 degrees Celsius for about 24 hours with aeration. The yeast was then separated by centrifugation at 5,000-15,000 rpm for 10 minutes at 24-32 degrees Celsius. A yeast slurry was then prepared by mixing the yeast 0.5-10% with 0.5-3% natural polymer solution. The immobilized yeast beads were then prepared by adding this solution dropwise into a curing solution of 0.05-0.3 M calcium chloride solution. The beads were kept in this solution overnight at a temperature of 4 degrees Celsius. The immobilized yeast beads were then separated by decanting the solution and washed with distilled water several times. The beads were then dehydrated at a temperature of 24-36 degrees Celsius for 2-20 hours to obtain stable yeast crystals having a moisture content of 5-30%. These crystals were activated by incubation in 5-8% molasses solution for 2-48 hours at 24-32 degrees Celsius. The yeast crystals were then separated by draining this aqueous solution. Sodium alginate 2% was generally used in preparing the yeast slurry. However, the reference does not teach selecting a culture from activated sludge.

Yuan teaches the immobilization of microbial cells in polymeric beads. The process of the reference can be used effectively to immobilize yeast, as well as activated sludge microorganisms and waste water treatment microorganisms (Col. 2, line 63 – Col. 3, line 5).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the microbial consortia obtained from wastewater treatment plants as taught by Yuan with the method of Ramakrishna et al. because Yuan teaches that both yeast and waste water microorganisms can be used for immobilization onto beads. Therefore, one could have substituted wastewater microorganisms for the yeast in Ramakrishna et al. with a reasonable expectation of success. It would also have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the specific aeration of 5 ml/minute. The selection of this parameters merely represents an optimization of the assay protocol and does not patentably distinguish the claimed invention over the prior art of record. One of skill in the art would easily be capable of selecting an appropriate aeration rate that promotes yeast growth. Further, the reference discloses the use of 1 N solutions to adjust pH, as opposed to 0.1 N as claimed. However, it would have been obvious to use 0.1 N solutions with the invention of the reference because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In this case, the use of a less concentrated solution allows for the concentration of the media to be adjusted at a more gradual rate than if using a more concentrated solution, with the selection of the preferred concentration well within the skill of those in the art.

10. Claim 24 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Moreton et al. (US Pat. 4,778,630) and Shimizu et al. (US Pat. 4,355,111).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast

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crystals, as previously discussed. However, the references do not teach the specific components of the growth media or glucose as the activation solution.

Moreton et al. teach the use of a growth medium comprising potassium dihydrogen orthophosphate, disodium hydrogen orthophosphate, yeast extract, glucose, ammonium chloride, and urea (Col. 4). The reference does not teach sodium bicarbonate or tryptone in media.

Shimizu et al. teach a growth medium comprising sodium bicarbonate and tryptone (claims).

It would have been *prima facie* obvious to one of ordinary skill in the art to use the growth media of Moreton et al. with the modified method of Ramakrishna et al. and Yuan because the selection of the growth media merely represents an optimization of the assay protocol that does not patentably distinguish the claimed invention over the prior art. One of skill in the art would easily be able to select an appropriate growth media for culturing various microorganisms. In addition, although Moreton et al. does not specifically teach tryptone, it allows for the use of other carbon sources, of which tryptone is an example, and Shimizu et al. teach the use of tryptone in media for the growth of microorganisms. In addition, Shimizu teaches sodium bicarbonate in media, which one of skill in the art could have easily substituted for the salts in the media of Moreton with a reasonable expectation of success, as calcium in calcium chloride and sodium in sodium bicarbonate are metals belonging to adjacent periods in the periodic table with similar properties. Furthermore, it would have been obvious to substitute dipotassium hydrogen orthophosphate for the disodium hydrogen orthophosphate in Moreton et al. because sodium and potassium belong to the same period in the periodic table, and one of skill in the art could reasonably expect them to have very similar properties.

11. Claim 29 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Husain et al. (US Pat. 6,361,695).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach the termination of growth at an MLSS of 14,500-15,500 mg/liter.

Husain et al. teach a wastewater treatment system wherein when the MLSS reaches levels of 15 g/l (15,000 mg/liter), some of the mixed liquor is removed from the bioreactor. The MLSS levels must be below this level for effective effluent treatment.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the MLSS levels of Husain et al. with the modified method of Ramakrishna et al. and Yuan because after an MLSS of 15,000 mg/liter has been reached, optimal conditions for effluent treatment and growth of microbes no longer exist.

12. Claim 35 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,420,146 in view of Yuan (US Pat. 6,153,416) as applied to claims 20, 22-23, 25-28, 30-34, and 36 above, and further in view of Kikuta et al. (US Pat. 5,990,191).

Ramakrishna et al. and Yuan teach a modified method for the preparation of stable yeast crystals, as previously discussed. However, the references do not teach glucose as the activation solution.

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Kikuta et al. teach a glucose solution for the activation of carriers with microorganisms immobilized thereon (Col. 10).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to substitute glucose as the activation solution as taught by Kikuta et al. for molasses as taught by Ramakrishna et al. because both are very well known carbon sources, and Kikuta et al. teach that glucose can be used for activation, which would provide one of skill in the art a reasonable expectation of success in making the substitution.

Response to Arguments

13. Applicant's arguments filed 1/10/05 have been fully considered but they are not persuasive.

14. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

15. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In addition, applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art

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disclosed by the references cited or the objections made. Applicant has merely described the references and concluded that the combination of references does not lead one of skill in the art to the claimed invention.

Conclusion

Claims 20 and 22-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
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2/4/05